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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,735	07/12/2001	William D. Suval	845642-1	5339

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EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

**Office Action Summary**

Applicati n No.

09/905,735

Applicant(s)

SUVAL, WILLIAM D.

Examiner

Paul A Roberts

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7 and 8 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 6 and 9-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to the apparatus of a vessel harvester, classified in class 606, subclass 159.
- II. Claims 13-22, drawn to a method of using the vessel harvester, classified in class 606, subclass 190.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to practice another materially different process. The apparatus could be used to strip the tributary veins from the central vein of a leaf. In this example no incisions would be necessary.

This application contains claims directed to the following patentably distinct species of the claimed invention:

The method of removal of the sheath catheter

- Spiral scored catheter, as shown in figure 1
- Side scored catheter, as shown in figure 9

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims none appear generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Brian Berliner on Sept 29<sup>th</sup>, 2002 a provisional election was made without traverse to prosecute the invention of the longitudinally scored catheter apparatus, claims 1-3 & 5-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4 & 13-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the guide wires must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: items 49, 57 are not described. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 5, & 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Perkins, US patent # 5,970,982.

5. Regarding claim 1, Perkins discloses a vessel harvester comprising all the parts the applicant has claimed.

<b>Applicant's Part</b>	<b>Perkin's Analogous Part</b>	<b>Location</b>	<b>Part number</b>
Stenting catheter	Outer Catheter	Column 5, line 63	12
Sheath catheter	Fluid removal channel	Column 5, line 17	27
Cutting Tube	Removal channel	Column 5, line 31	25
Distal end <sup>1</sup>	Distal end	Column 5, line 18	22

6. Regarding claim 5, the Perkins device contains a cutting tube that has a sharp edge. It is well known that one bevels an edge by grinding it to form a sharp edge.

7. Regarding claim 7, the Perkins device comprises a vessel collecting lumen. Though Perkins does not specifically describe the vessel collecting lumen as part of the cutting tube;h since the lumen is inside the outer catheter, it must be part of the cutting tube<sup>2</sup>.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>1</sup>As shown in figure 3, item 25 is connected to item 22.

<sup>2</sup>Column 7, Lines 40-45

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins.
10. Regarding claim 8, the cutting tube and collecting tube must be long enough to fully capture a vein, and short enough to be manageable. Perkins does not disclose the length for the cutting tube nor the collecting lumen, nor does Perkins specify the length of the diameter of the cutting tube. However, the workable range of a vessel dissector ranges from greater than 0 cm to less than or equal to the length of the largest vein. The workable range of a vessel dissector's cutting tube diameter ranges from the smallest veins .05 mm to the slightly greater than the width of the vena cava. Since, the claimed range is within the workable range of a standard vessel harvester, it would have been obvious to one skilled in the art at the time of the invention to create the vessel harvester within the standard physiological dimensions of a vessel harvester.

#### *Allowable Subject Matter*

11. Claims 2, 3, 6, 9, 10, 11, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
12. The following is a statement of reasons for the indication of allowable subject matter:
  - The prior art fails to disclose the use a peel-away catheter used in a vessel harvester.
  - The prior art fails to disclose the use of connecting prongs connecting a cutting tube to the distal end of a sheath catheter with the limitations of claim 1.
  - The prior art fails to teach the use of a guide wire with the limitations of claim 1.

#### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


US 5373840 A	Endoscope and method for vein removal
US 5695514 A	Method and apparatus for harvesting blood vessels
US 5899913 A	Methods and devices for blood vessel harvesting
US 5913866 A	Devices and methods for harvesting vascular conduits
US 5928135 A	Method and devices for endoscopic vessel harvesting
US 5928138 A	Method and devices for endoscopic vessel harvesting
US 5938680 A	Devices and methods for harvesting vascular conduits
US 5968066 A	Methods and devices for blood vessel harvesting
US 5970982 A	Minimally invasive biological vessel harvesting method
US 6036713 A	Instruments and methods for minimally invasive vascular procedures
US 6042538 A	Device for endoscopic vessel harvesting
US 6059802 A	Dissecting retractor for harvesting vessels

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts  
October 21, 2002

  
**MICHAEL J. MILANO**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**